

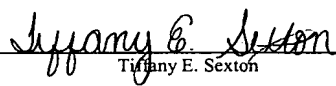


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PATENT

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Serial No.: 09/662,203)
Applicants: SMITH and McAULEY)
Filed: September 14, 2000)
For: BREATHING ASSISTANCE)
APPARATUS)
Examiner: G. DAWSON)
Art Unit: 3761)
Attorney Docket No.:)
1171/38911/80)

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RESPONSE TO OFFICE ACTION

Asst. Commissioner for Patents
Washington, D.C. 20231

Sir:

This is responsive to the Office Action dated August 6, 2003. A Petition for a Two-Month Extension of Time is concurrently submitted herewith to extend the date for response up to and including January 6, 2004.

Allowable Subject Matter

The Examiner indicated that claims 1-7 are allowed and that claims 14-21 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Claim Rejections – 35 U.S.C. §102(b)

Claims 8, 10 and 12 were rejected under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 4,088,131 to Elam. Reconsideration and allowance of the claims is respectfully requested in view of the remarks herein.

Claim 8 specifies “a pressurized gases supply for supplying a continuous positive pressure above ambient”.

In the Office Action, the Examiner stated that a conventional oxygen tank “clearly has the ability to supply oxygen gas continuously at a pressure above ambient.” The Examiner has made this statement even though previously the Examiner had stated that “there would not be a need for the device to provide positive pressure to the patient during exhalation” (see the Office Action dated February 24, 2003). Applicants agree with the Examiner’s earlier statement in the Office Action dated February 24, 2003. In Elam, there would not be a need for the device to provide positive pressure to the patient during exhalation. Therefore, Applicants submit that it would not be obvious to modify Elam to supply oxygen gas at a continuous pressure above ambient during exhalation and claim 8 is not anticipated and is not rendered obvious by Elam.

In addition, Applicants submit that an oxygen tank will only provide pressure at the outlet to the oxygen tank. With the system of the present invention as defined in claim 8, if an oxygen tank was used to provide pressure and gas to the patient, substantial pressure would be lost by the time the gas reached the patient, such that any gas supplied would not assist treatment of the patient. As defined in claim 8, “a pressurized gases supply for supplying a continuous positive pressure above ambient” is defined, and the pressurized gas supply causes positive pressure above ambient to reach the patient. Applicants submit that the oxygen tank pressure in Elam, if traveling through a gas delivery means (e.g., a plastic

tubing or the like), would be unable to supply the requisite gas pressure to treat a patient appropriately.

Therefore, Applicants respectfully submit that Elam does not anticipate claim 8, and cannot be modified to render obvious claim 8. Reconsideration and allowance is requested.

In addition, Applicants re-submit their earlier arguments. Claim 8 requires modes of operation during inhalation and exhalation of the user. Elam does not disclose a device for use with a spontaneously breathing patient. Thus, the requirements of claim 8 including modes of operation during inhalation and exhalation are not pertinent to the disclosure of Elam. Applicants submit that it is clear that the device of Elam would not be practical to employ in a situation where the patient is spontaneously breathing. During exhalation of the patient, claim 8 requires that the flow of gas from the first opening are directed to the first auxiliary outlet. In Col. 4 of Elam, the second phase of operation is such that valve 52 is closed. Thus, during spontaneous exhalation of the patient, Elam does not disclose the flow of gas from the pressurized gas supply to be vented externally through an outlet.

Applicants submit that it is also unclear what would occur in Elam during spontaneous inhalation. Claim 8 requires that the flow of gas from the first opening is directed to the second opening. If the flow of oxygen has not been selected, Applicants submit that it is possible that the patient would suffocate if the bag was not compressed. If oxygen were selected during phase three, it is free to flow out through port 30. Thus, the benefit of CPAP treatment would be lost because the positive pressure could not be maintained. Applicants submit that it is clear from the disclosure of Elam that the device would not work in the case of a spontaneously breathing patient and, therefore, that the two modes of operation required by claim 8 during exhalation and inhalation of a spontaneously breathing user would not be met. Accordingly, Applicants submit that claim 8 is not

anticipated by and are not rendered obvious by Elam. Reconsideration and allowance of claim 8 is respectfully requested.

Claims 10 and 12 are dependent upon claim 8 which Applicant submits is in condition for allowance. Reconsideration and allowance of claims 10 and 12 is respectfully requested.

Claim Rejections – 35 U.S.C. §103

Claims 9, 11 and 13 were rejected under 35 U.S.C. §103 as being unpatentable over Elam. Claims 9, 11 and 13 are dependent upon claim 8 which Applicant submits is in condition for allowance. Reconsideration and allowance of claims 9, 11 and 13 is respectfully requested.

In addition, Applicants re-submit their earlier arguments. Claims 9, 11 and 13 require humidifying the gas before delivery to the user. Elam does not suggest using humidified gas. If humidified gas were introduced to bag 13 in Elam, it is likely that condensation would occur resulting in welling of water and possible malfunction of the device. Also, during the second phase of operation described in column 4 of Elam, Applicant submits that it is not apparent if the user was inhaling during this period how such humidified gas would be delivered. Accordingly, Applicant submits that claims 9, 11 and 13 are not rendered obvious by Elam. Reconsideration and allowance is respectfully requested.

In view of the above Remarks, Applicant respectfully submits that the claims of the application are allowable over the rejections of the Examiner. Should the Examiner have any questions regarding this Amendment, the Examiner is invited to contact one of the undersigned attorneys at (312) 704-1890.

Respectfully submitted,

Dated: Dec. 12, 2003

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